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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/560,127 | 12/09/2005 | Ralf Ragnar | 101077 - 1P US | 2806 |

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COZEN O'CONNOR, P.C.
1900 MARKET STREET
PHILADELPHIA, PA 19380

| EXAMINER | |
|---|---|
| VALENROD, YEVGENY | |
| ART UNIT | PAPER NUMBER |
| 1621 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 02/15/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/560,127 | RAGNAR ET AL. | |
| | Examiner | Art Unit | |
| | Yevgeny Valenrod | 1621 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/09/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treatment dislipidemia and type 2 diabetes, does not reasonably provide enablement for prevention of dislipidemia and type 2 diabetes The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

(A) The breadth of the claims;
(B) The nature of the invention;
(C )The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

*The breadth of the claims*

Claims 8 and 9 are drawn to a method for preventing dislipidemia (claim 8) and type 2 diabetes (claim 9) by administering the compound of claim 1 or claim 2.

*The state of the prior art*

The examiner notes that the art does not recognize preventive therapeutic agents for dislipidemia or type 2 diabetes. Applicants are invited to provide evidence to the contrary. In any event, the examiner notes that there is no art provided of record, evidence set forth in the disclosure, or correlation establishing some nexus to support preventive administration or therapy between the art and the instant disclosure to support the alleged disease preventing applicability of the Magnesium or Calcium salts of the instant invention.

*The level of one of ordinary skill*

The skilled artisan in this field is that of an MD and/or a PhD skilled in the development and treatment of dislipidemia and type 2 diabetes.

*The level of predictability in the art*

The examiner acknowledges the probability and predictability that the instantly claimed salts have applicability in treating dislipidemia or type 2 diabetes. There is not seen sufficient data to substantiate the assertion that dislipidemia or type 2 diabetes may be prevented by the compounds of the instant invention. One skilled in this art would not predict from the disclosure provided that dislipidemia or type 2 diabetes can be prevented in view of the data and examples provided.

*The amount of direction provided by the inventor.*

The instant specification is not seen to provide adequate guidance, which would allow the skilled artisan to extrapolate from the same to establish enablement for the prevention of dislipidemia or type 2 diabetes. There is not seen guidance as to how the skilled artisan would formulate the requisite active agents and use it in methods for the prevention of either of the claimed diseases.

There is not seen sufficient guidance, which would teach the skilled artisan how to administer, said active agents in methods for preventing dislipidemia or type 2 diabetes. To treat said diseases appears to be the limit of the applicability of the claimed compounds.

*The existence of working examples*

There are no working examples provided in the specification

*The quantity of experimentation needed to make or use the invention based on the content of the disclosure*

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable the prevention of any disease or conditions and the skilled artisan would not extrapolate preventive efficacy from the compounds instantly claimed. Nor is this data alone recognized in the art, as sufficient data to assert compounds with a specific activity would be expected to prevent dislipidemia or type 2 diabetes.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindstedt et al. (US 2005/0171204).

Instant claims are directed to a calcium or a magnesium salt of (2S)-2-ethoxy-3-(4-{2-[hexyl(2-phenylethyl)-amino]-2-oxoethoxy}phenyl)propanoic acid (from now on Compound I). Various forms of compound I are claimed in claims 2-6. Claims 7 and 12 are directed to a pharmaceutical formulation comprising compound I. Claim 8 and 9 are methods of treating or preventing dislipidemia and diabetes type 2 by administering a compound of formula I. Claim 11 is a pharmaceutical composition comprising compound I and another therapeutic agent.

*Scope of prior art*

Lindstedt et al. teach the free acid of compound 1 (page 2, paragraph [0021]). They also teach alkaline earth metal salt of the said acid (alkaline earth metals include Mg and Ca) (paragraph [0023], line3) and crystalline forms (paragraph [0022]). Alkaline metal earth metal counterions are pharmaceutically inactive counterions. In paragraph [0024], lines 1-3, Lindstedt et al. teach the hydrated form of the compound. Paragraph [0115] describes pharmaceutical compositions, [0052] describes compound I and another therapeutic agent. Methods of using the compound of the instant invention in

treatment of medical conditions is described [0044] (type 2 diabetes) and [0045] (dislipidemia).

*Ascertaining the difference between prior art and the instant claims*

Lindstedt et al. teach alkaline salt of the free acid of compound I. However they do not specifically teach Magnesium or Calcium salts. They also do not teach $[CaCl]^+$ counterion.

*Obviousness*

Alkaline earth metal salts of pharmacologically active compounds are common in the art. Lindstedt et al. broadly teach salts of the compound of formula I and specifically mention alkaline earth metal salts. The instant invention claims particular alkaline earth metal salts, Magnesium and Calcium. The claimed salts are not patentable over Lindsdedt et al. absent unexpected results arising from the use of Magnesium or Calcium. Applicant claims that the salts of the instant invention can be used as medicaments for dylipidemia and type II diabetes, which is the same utility Lindstedt et al. describe for their salts. In the specification, on page 2, applicant compares the compounds of the instant invention to those found in PCT/GB02/05743. The alleged unexpected result of the magnesium or sodium salt is that it can be made into a crystalline form. Examiner would like to note that the compounds of PCT/GB02/05743 are structurally different from those of the instant invention. Therefore, the alleged unexpected result is not applicable to the instant case. In order to claim unexpected result the applicant needs to supply evidence that would make clear what advantage the Ca or Mg salt of compound I has over the salts described by Lindstedt et al.

***Conclusion***

Claims 1-12 are pending

Claims 1-12 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yevgeny Valenrod
Patent Examiner
Technology Center 1600

for Thurman Page
Supervisory Patent Examiner
Technology Center 1600

S. Kumar
Primary Examiner
1621